

Consent Document Example

(These elements must be included in any Cover Letter)

(Title of Study)

You are invited to participate in a study of (state what is being studied). My name is _____ and I am a (graduate/student/faculty/researcher) at (name of Institution/University and Department). (If a student, state how the study relates to your program of work, i.e. report, thesis, dissertation.) I/We hope to learn (state what the study is designed to discover or establish). You were selected as a possible participant in this study because (state why and how the subject was selected). If you decide to participate, you will be one of (give number of subjects being studied) subjects chosen.

If you decide to participate, I/we (or: _____ and associates) will (describe the procedures to be followed, including their purposes, how long they will take, and their frequency. Describe the risks, discomforts, and inconveniences reasonably to be expected, and any benefits reasonably to be expected).

(Describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.)

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. (If you will be releasing information to anyone for any reason, you must state the persons or agencies to which the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure.)

Your decision whether or not to participate will not influence your future relations with the Department of State Health Services or (identify by name any other institution(s) and/or agency(s)). If you decide to participate, you are free to discontinue participation at any time and no harm will come to you. *

If you have questions regarding your rights as a research subject, please call the (University Institutional Review Board, phone number) or the Department of State Health Services Institutional Review Board at 1(888) 777-5037. If you have any questions regarding participation in this study, please ask us. If you have any additional questions later, you may contact (name of study investigator/coordinator, toll free phone number, in addition, give the address and phone number of your dissertation Chair, if appropriate). You will be offered a copy of this form to keep.

You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and have decided to participate. You may withdraw at any time after signing this form, should you choose to discontinue participation in this study. **

Signature of Participant

Date

Signature of Parent or Legal Guardian

Date

(NOTE: This line should not appear on forms that will be given to subjects consenting for themselves.)

Signature of Child

Date

(NOTE: Required when child is 7 years of age or older, or a separate Assent Form may be used, when appropriate)

Signature of Witness (when appropriate)

Date

Signature of Investigator

Date

If you are collecting your data by means of a mail-out questionnaire, you may wish to substitute the following format for these paragraphs. (All information from the Consent Form must be included in your Cover Letter as well.)

* You are under no obligation to participate in the study. Your completing and returning the questionnaire will be taken as evidence of your willingness to participate and your consent to have the information used for purposes of the study.

** You may retain the cover letter and this explanation about the nature of your participation and the handling of the information you supply.